





PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Ref. No. 96-223-ZZ)

|                                      |   |   |
|--------------------------------------|---|---|
| In re the Application of:            | ) |   |
|                                      | ) |   |
| <b>Tamburini et al.</b>              | ) | Examiner: <b>not yet assigned</b>       |
|                                      | ) |   |
| Application No.: <b>09/974,026</b>   | ) | Group Art Unit: <b>not yet assigned</b> |
|                                      | ) |   |
| Filing Date: <b>October 10, 2001</b> | ) |   |
|                                      | ) |   |
| For: <b>Human Bikunin</b>            | ) |   |
|                                      | ) |   |

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

This statement is filed under 37 C.F.R. §§1.97-1.98, in compliance with the duty of disclosure set forth in 37 C.F.R. §1.56. A PTO Form 1449 is enclosed. In addition, copies of the references listed on the Form 1449 are enclosed. These documents contain information that the Patent Office may consider to be important in deciding whether to allow the present application to issue as a patent.

In accordance with MPEP §§ 609 and 707.05(b), it is requested that the references cited (including any cited in the specification which are not repeated on the enclosed Form 1449) be given thorough consideration and that they be cited of record in the prosecution history of the present application by initialing on the Form 1449. Such initialing is requested even if the Patent Office does not consider a cited reference to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not

believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Two of the references enclosed are entirely in a foreign language. English translations of the references are not available to the applicants. However, the English Medline database entries for the two references are as follows:

Reference 49:

Arzneimittelforschung 1975 Jan;25(1):110-6

**[Effect of the protease inhibitor aprotinin on pulmonary function and on the inhibitory activity of sputum in patients with chronic obstructive bronchitis]**  
[Article in German]

**Rasche B, Marcic I, Ulmer WT.**

It has been investigated whether a substitution of protease inhibitor deficiency is indicated in case of chronic obstructive airway disease. As a therapeutic possibility, apronitin isolated from bovine organs (tyasylol), which in vitro inhibits sputum proteases up to 80 per cent was tested. Besides infusion, inhalation was chosen for application by which a protease inhibition could be attained. We observed an inhibition of the course of illness associated with a good tolerance of the preparation. Whether a therapy applying the addition of protease inhibitor is reasonable in the long run in chronic diseases cannot yet be concluded from these investigations.

Reference 52:

Med Klin 1977 Feb 4;72(5):145-60

**[Drug therapy of bronchosecretolytic disorders]**  
[Article in German]

**Schmidt OP.**

Publication Types:

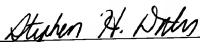
Review

If there is any fee due in connection with the filing of this Statement, Applicants hereby authorize the Commissioner to charge the fee to Deposit Account No. 13-2490.

Respectfully submitted,  
McDonnell Boehnen Hulbert & Berghoff

Dated: March 12, 2002

By:

  
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MAR 22 2002

PATENT &amp; TRADEMARK OFFICE

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

|                      |                  |
|----------------------|------------------|
| Application No.      | 09/974,026       |
| Filing Date:         | 10/10/2001       |
| First Named Inventor | Tamburini        |
| Group Art Unit       | Not yet assigned |
| Examiner Name        | Not yet assigned |
| Attorney Docket No.  | 96-223-ZZ        |

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| Sheet | 1 | Of | 4 |
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## U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. <sup>1</sup> | U.S. Patent Document |                                   | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Figures Appear |
|--------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
|                    |                       | Number               | Kind Code <sup>2</sup> (if known) |   |  |   |
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| Examiner Signature | Date Considered |
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| FOREIGN PATENT DOCUMENTS |                       |                         |                     |   |  |   |                |
|--------------------------|-----------------------|-------------------------|---------------------|---|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document |                     | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines Where Relevant Passages or Figures Appear | † <sup>2</sup> |
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| Examiner Initials*                                 | Cite No. <sup>1</sup> | Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published            |  |  | † <sup>2</sup> |
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| P104 2-2007       |        | OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS, CONT.  |    |
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|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English translation is attached.

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**OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS, CONT.**

58

WOJTA et al. (1994) "Hepatocyte growth factor stimulates expression of plasminogen activator inhibitor type 1 and tissue factor in HepG2 cells" Blood 84:151-157 (Abstract).

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